



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request: National Children's Study (NCS) Data Archive and Repository (NICHD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Jack Moyer 6100 Executive Boulevard, Rockville Pike, MD 20891 or call 301- 594-8624 or E-mail your request, including your address to: moyerj@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: National Children's Study (NCS) Data Archive and Repository, 0925-NEW, National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: The primary use of this data archive and repository is to facilitate, document, track, monitor, and evaluate the access of NCS Vanguard Study data previously collected. There are two planned levels of data access associated with NCS Vanguard Study data: (1) through a de-identified dataset containing key variables. Access requirements for the de-identified dataset would be modest, requiring that the investigators, promise not to attempt to re-identify participants, agree to cite the NCS as the source of the data, and submit a copy of any paper submitted or

published using the data; (2) through a secure, virtual data enclave wherein users could access and analyze data, provided that they describe their research plan, submit IRB approval documentation, complete a Data User Agreement (DUA) DUA, and agree to submit a copy of any paper submitted or published using the data. In the planned virtual data enclave, the investigator cannot download any participant-level data for use outside of the protected analytic environment. Upon approval of the research project the data files specified in the DUA would be placed in the investigator's project space within the data enclave by the enclave staff. Final analytic results would be screened by the enclave staff for identifiable information prior to release back to the investigator.

There is no plan to publish the data collected under this request. These data are for internal monitoring purposes to assess the enclave resource requirements.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 154.

Estimated Annualized Burden Hours

Form	Number of Respondents	Frequency of Response	Average Time Per Response (in hours)	Total Annual Burden Hour
De-identified data access	300	1	10/60	50
Enclave data access	100	1	1	100
Additional data access	50	1	5/60	4

Dated: April 10, 2015

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National Institutes of Health

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